

# Effects of high dose vitamin D supplementation on muscle mass and muscle strength in frail elderly people

<b>Submission date</b> 11/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/04/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

### Study objectives

Vitamin D improves muscle-mass and -strength which improves overall quality of life in patients with low serum vitamin D levels.

Please note that as of 13/07/10 this record was updated to included changes made to the protocol during the planning phase of the trial (i.e. between the time of registration and the beginning of the recruitment phase). All updates can be found in the relevant field with the above update date.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Added 13/07/10:

The Medical Ethics Review Committee (Medisch Ethische Toetsings Commissie), Erasmus Medical Centre approved on the 24th of July 2007 (ref: MEC-2007-160)

### Study design

Randomised placebo controlled parallel group double blind trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Quality of life

### Participant information sheet

Copies of the Investigational Medicinal Product Dossier (IMPD) and 2007 MEC approval are available on request. Please use contact details below.

### Health condition(s) or problem(s) studied

Hypovitaminosis D on muscle mass and strength

### Interventions

Current information as of 13/07/10:

Patients were randomised to receive either

1. 1800IU cholecalciferol (vitamin D3) daily

## 2. Placebo daily

Medications were used for a period of six months. The end date for inclusion into this trial was December 2009.

Initial information at time of registration

Individuals are randomised to receive either:

1. 1200 IU vitamin D/day and 1000 mg calcium/day
2. Placebo medications and 1000 mg calcium/day

Medications will be used for a period of six months.

### **Intervention Type**

Supplement

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

High dose vitamin D

### **Primary outcome measure**

Differences in muscle strength (handgrip strength and quadriceps strength) between treatment and control group.

### **Secondary outcome measures**

1. Changes in mobility:
  - 1.1. Timed up and go test
  - 1.2. Walking distance
2. Quality of life (using the health assessment questionnaire)
3. Falls

### **Overall study start date**

01/04/2007

### **Completion date**

01/04/2008

## **Eligibility**

### **Key inclusion criteria**

1. Frail elderly people, aged greater than 65 years
  2. Living in homes for the elderly
  3. Serum vitamin D level less than 50 nmol/l
- Added 07/04/2011:
- 4: Stable health (including no history of recurrent falling or recent fracture).

### **Participant type(s)**

Patient

### **Age group**

Senior

**Sex**

Both

**Target number of participants**

300

**Key exclusion criteria**

1. Not able to perform muscle strength measurements
2. History of kidney stones, renal insufficiency (less than 40%)
3. Primary hyperparathyroidism
4. Dementia (Mini Mental State Examination [MMSE] less than 20/30 points)
5. Life expectancy less than six months
6. Neurodegenerative disorders (Parkinsons, Amyotrophic Lateral Sclerosis [ALS])
7. Use of the following medications:
  - 7.1. Vitamin D
  - 7.2. Bisphosphonates
  - 7.3. Steroids

**Date of first enrolment**

01/04/2007

**Date of final enrolment**

01/04/2008

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Erasmus Medical Centre**

Rotterdam

Netherlands

3000 CA

## **Sponsor information**

**Organisation**

Erasmus Medical Centre (Netherlands)

**Sponsor details**

Department of Geriatrics

P.O. Box 2040

Rotterdam  
Netherlands  
3000 CA

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.erasmusmc.nl/>

**ROR**

<https://ror.org/018906e22>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Erasmus Medical Centre (Netherlands)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration